

1.26.2 Minor Upgrade and Configuration Release Items

July/August 2022

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Icons below indicate the application(s) impacted by the enhancement.



ESTR-IRB



Agreements-DUA

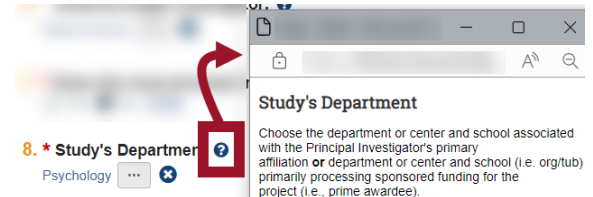
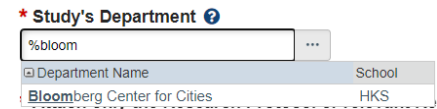


Data Safety



OAIR

Cross-Suite Enhancements

What has changed...	What it means...	How it looks (as applicable) ...
SmartForm		
Help text populated throughout the SmartForms   	Per-question, in context help text is visible by clicking the question mark icon beside relevant items in SmartForms.	
Department selection enhancements   	Selection options are optimized for speedier display for selection on SmartForms. The following departments are additionally visible for accurate selection across the suite: • HKS-Bloomberg Center for Cities • HUA-Wyss	
Additional help text when relating projects   	Help text instruction is added to clarify that it is sometimes appropriate to accompany an amendment/modification with new relationships.	

Notification header and footer updates



For each application, the basic related site banner will display in the header, with the source system URL in the footer.

Miscellaneous

Added navigation tab for Research Administration Portal



A new tab in the Suite navigation bar links directly to the Research Administration Portal.



Report page updated to show reports with special Custom Report tag



Currently as new custom reports are created, they must be manually added to the Reports page template. The page template is now configured to display all reports with the Custom Report tag so new reports can be added as needed, without configuration release. Note that resulting updates in IRB mean that the Custom Reports tab name is now Harvard-Custom Reports and reports are listed in alphabetical order.

Office 365 integration enhancements



This issue fixes the problems with attempting to edit documents in-browser at appropriate times in the review process.

Internal server error bug fix

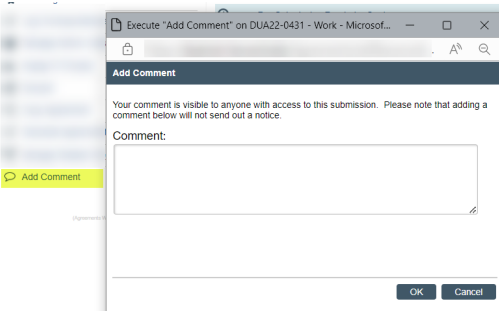
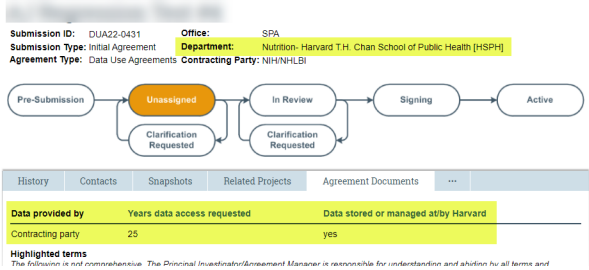


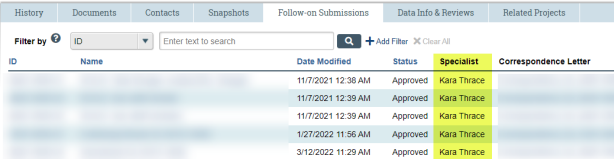
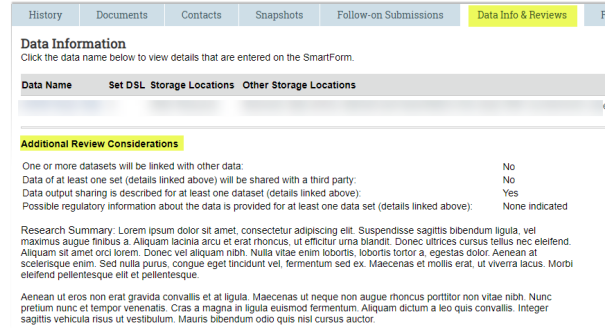
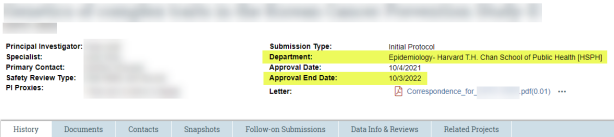
When attempting to save changes to a SmartForm, an internal server error would display because the date-time format cannot be converted from non-US English (DD/MM/YYYY HH:MM:SS) to US English (MM/DD/YYYY HH:MM:SS). This is fixed in Safety, IRB, and Agreements but may still present in OAIR.

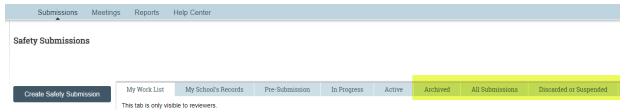
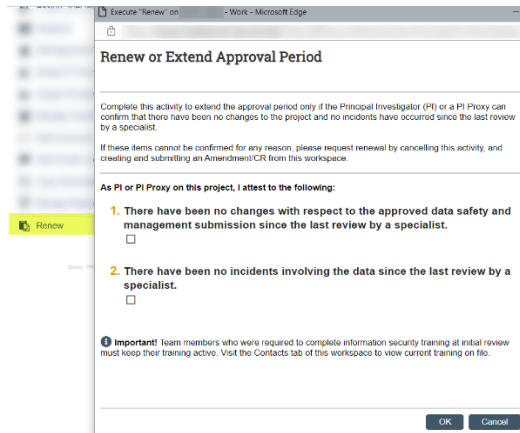
What has changed...	What it means...	How it looks (as applicable) ...																																		
SmartForm																																				
Study Team Members: New "administrative only" option	When adding or changing team member roles, “ESTR-IRB Administrative Support Only (no access to participants or data)” can now be selected. This option allows for easier management of persons that need access to the record but is NOT required to take training. Help text in this section of the form is also updated.																																			
External IRB: Clarifications related to External IRB review	The following sections of the External IRB SmartForm (when requesting Harvard reliance on another IRB) are updated: - When selecting reliance on the Basic Information page of the SmartForm, instructional text displays regarding what types of review allow for reliance. - A grammar error on the Harvard data management question has been corrected. - Help text added to: - Indicate the rare circumstances that it is appropriate to choose reliance for a single site-type study. - Clarify what is needed for the rationale for reliance.																																			
Study Update: Instruction clarification	The last part of on-screen instruction has been updated to clarify that "Site Modification" is only available for multi-site or collaborative research.																																			
Activities																																				
Assign PI Proxy available before initial approval	Prior to update, the PI could only assign proxy after initial submission. Now, the PI can assign proxy (from the list of study team members) at any point in the draft, review, and approval process.																																			
Additional help text to ancillary approval activity prompts	Additional help to comment space and document upload, to indicate that items added are visible to the study team.																																			
Workspaces																																				
Submission: New information on the Contacts tab	The following two changes are visible on the Contacts tab of submission workspace: - Each team member is listed with a date modified, intended to show when any additions or revisions occur during review or modification. - Only current active training displays beside each team member. - If no training is visible, there is no active training on file.	HistoryFundingContactsDocumentsReviewsSnapshots Principal Investigator <table><thead><tr><th>Name</th><th>School/Unit</th><th>Dept Affiliation</th><th>Title Email</th><th>Financial Interest</th><th>Current Active Training (with expiry)</th><th>Profile Link</th></tr></thead><tbody><tr><td>Walter Bishop</td><td>Harvard Kennedy School (HKS)</td><td></td><td>wbishop@fringe.tst.no</td><td></td><td>CTI - Social & Behavioral - Refresher (6-28-2025) CTI - Good Clinical Practice (6-8-2025)</td><td>Walter Bishop</td></tr></tbody></table> Study Team Members Filter byFirst NameLast NameSchool/UnitDept AffiliationTitle EmailDate ModifiedRoles on StudyFinancial InterestCurrent Active Training (with expiry)Profile Link <table><tbody><tr><td>Peter</td><td>Bishop</td><td>Harvard Kennedy School (HKS)</td><td></td><td>pbishop@fringe.tst</td><td>6/28/2022</td><td>Project Manager</td><td>no</td><td>CTI - Biomedical Research Investigators - Basic (6-28-2025)</td><td>Peter Bishop</td></tr><tr><td>William</td><td>Bell</td><td>Harvard Medical School (HMS)</td><td></td><td>wbell@fringe.tst</td><td>6/28/2022</td><td>ESTR-IRB Administrative Support Only (no access to participants or data)</td><td>no</td><td></td><td>William Bell</td></tr></tbody></table>	Name	School/Unit	Dept Affiliation	Title Email	Financial Interest	Current Active Training (with expiry)	Profile Link	Walter Bishop	Harvard Kennedy School (HKS)		wbishop@fringe.tst.no		CTI - Social & Behavioral - Refresher (6-28-2025) CTI - Good Clinical Practice (6-8-2025)	Walter Bishop	Peter	Bishop	Harvard Kennedy School (HKS)		pbishop@fringe.tst	6/28/2022	Project Manager	no	CTI - Biomedical Research Investigators - Basic (6-28-2025)	Peter Bishop	William	Bell	Harvard Medical School (HMS)		wbell@fringe.tst	6/28/2022	ESTR-IRB Administrative Support Only (no access to participants or data)	no		William Bell
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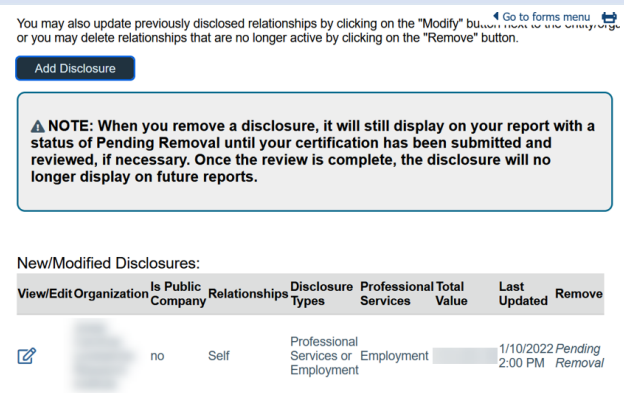
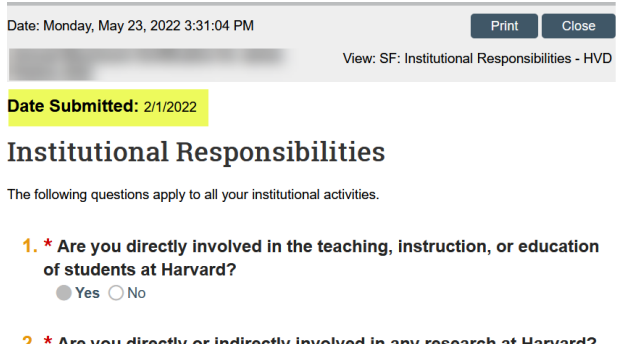
What has changed...	What it means...	How it looks (as applicable) ...
	○ Previous (or lapsed) training can be viewed by IRB office staff by clicking the profile link.	
Meetings: Past and Future meetings lists are sorted by date	To allow for easier navigation to recent and pending meetings, each of the meeting listing is sorted by date (most to least recent).	

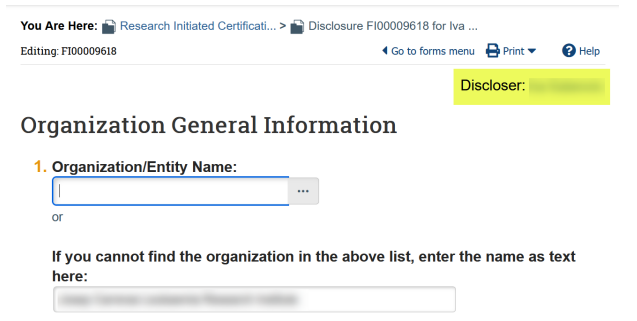
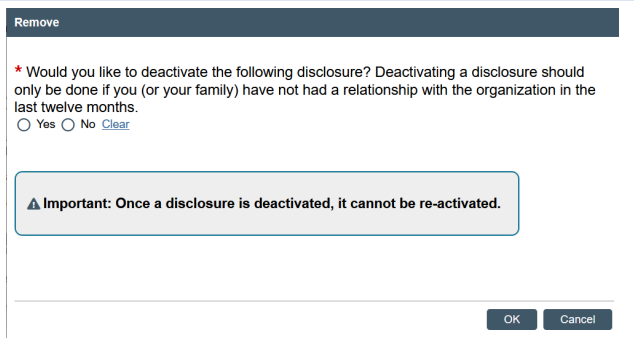
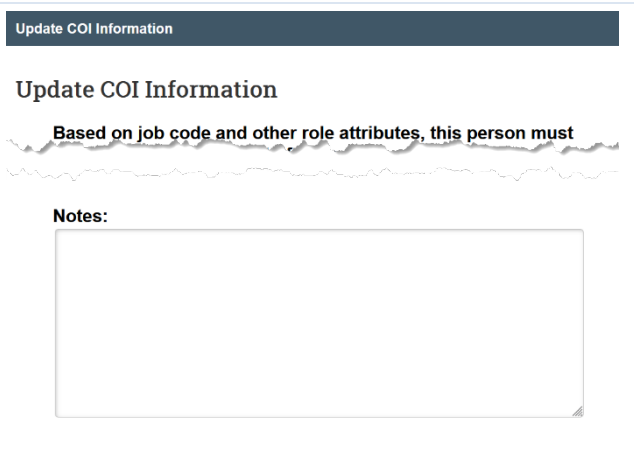
Agreements-DUA Enhancements

What has changed...	What it means...	How it looks (as applicable) ...
SmartForm		
New instruction at the time of organization entry	Additional instruction regarding how to find an organization displays beside the field for selecting contracting party, before using write-in.	
Activities		
Allow for Comments on Agreements	Added the ability to add a note (comment) on the workspace, without the need for a separate email or activity.	
Workspaces		
Submission: Improve visibility into related projects attributes that may impact review	The Agreement workspace is enhanced to show additional items: • School • Data provided by • Years requested	
Agreements: Set My Work list to display 50 per page by default	The worklist is often longer than 10 items and it would be helpful to see as complete a list as possible. Extended to 50 items per page to mitigate the need to often reset the default or page forward.	
Letters and Notifications		
Add notification on discard activity	New custom notification to the PI, Primary Contact, and proxies when a record is discarded.	
Revise response time exceeded notice	Reminder content revised to indicate that inactivity after six months requires action or the record will be terminated/discarded on the researcher's behalf.	

What has changed...	What it means...	How it looks (as applicable) ...
SmartForm		
Documents uploaded via revision on drafts should appear on the parent project after an Amendment/CR is approved	New documents that are added on submission as part of "upload revision" via Amendment/CR did not appear on the parent after Amendment/CR was approved (impacting both supporting documents and other study team members). This bug is now fixed, and updates will show as approved on the parent after review is completed.	
Revise the section where it is indicated if data is not stored at Harvard	The order of questions regarding data stored at Harvard and the presence of a contract has been revised for easier entry and review.	
Workspaces		
Submission: Add Specialist to Follow-On Submissions list	For easy reference, the name of the assigned specialist is now listed with each follow-on submission.	
Submission: Create special / simplified view for reference	Additional Review Considerations section has been added to the Data Info & Reviews tab for simplified access to information relevant for external reviewers who need to access basic information about the record.	
Submission: Revisions to top summary section	Revised "Last Day of Continuing Review Period" to "Approval End Date" (also impacts activities where this date is referenced). This is in an effort to make language consistent to the two types of activity that may extend the approval (renew OR continuing review).	
	Added Department and School to the view.	

What has changed...	What it means...	How it looks (as applicable) ...
Safety: Change the tab navigation on the submissions page	Changed the order and contents of tabs to increase ease of access. • Archived to include Closed and Lapsed • All Submissions moved to the right one position • Suspended and Lapsed changed to Discarded and Suspended and in right-most position	
Help Center: Update VPR links to go to new site address	The OVPR website was updated and the URL changes from vpr.harvard.edu to research.harvard.edu.	
Letters and Notifications		
Add notice to assigned reviewer when ancillary review completed	New notification to reviewer when ancillary review is completed.	
Determination letter revision	Standard determination letter template now includes basic information about Renew, Continuing Review, and Amendment/CR options for record update/approval extension.	
Notification of specialist assignment should show department for all submission types	The updated notice corrects the issue so that department displays in notice content for any submission type.	
Activity		
New “Renew” activity to allow for more automated renewal/ approval extension for relevant projects	For approved (not lapsed) projects, a researcher is able to confirm that there are no changes to a protocol and no incidents have occurred in the last year to easily renew the project. Upon successful completion of the activity, the approval end date is extended and a notification of confirmation is sent to the PI, Primary Contact, and proxies. Researchers can use Amendment/CR to request changes or share specific updates on approved projects, or request renewal of lapsed projects.	
Add more context to Approve Submission activity for reviewer reference	The prompt for comments on the Approve Submission activity (step 5) is updated to clarify “Text entered here will be included in the Determination Letter.	

What has changed...	What it means...	How it looks (as applicable) ...
SmartForm Added explanation related to disclosures Pending Removal	When a discloser removes a disclosure, that relationship will continue to display on the certification until it reaches a terminal state. The added explanation/instructions will clarify the disclosure removal process to disclosers. This explanation will only display when the discloser has relationships marked for removal.	
Clarifications to SmartForm instructions and questions	The following clarifications were made to instructions and questions on the SmartForm: - On the Disclosure General Information page, an explanation of the scope of the Professional Services or Employment category has been added above the list of activity and interest categories. In addition the link to the Definitions and Terms document has been moved above the list of categories. - On the Professional Services or Employment page, the link to the Definitions and Terms document has been moved to the top of the page. - On the Additional Disclosure Information page, the question regarding overlap between the organization and the discloser's University activities has been clarified. - On the Additional Disclosure Information and Institutional Responsibilities pages, the references to the IRB have been updated to clarify that the questions are referring to human subjects research overseen by the Institutional Review Board.	
Added Submitted Date to Default Certification Printer Version	The date the certification was submitted will now display at the top of the Default Printer Version if the certification has been submitted.	

What has changed...	What it means...	How it looks (as applicable) ...
Added Discloser's name to the SmartForm Pages	Previously, the discloser's name did not display on the SmartForm view. Now it will display in the top right corner on all the Disclosure SmartForm pages and the following Certification SmartForm pages: Disclosure Details, Research Information, and Additional Information. The name will not display for the discloser themselves.	
Activities		
Updated instructions on the Remove Disclosure activity	Previously the instructions on the Remove Disclosure activity did not accurately reflect Harvard policy on when relationships should be removed. The instructions have been updated to indicate that the discloser should only remove a disclosure if they have not had a relationship with the organization in the last twelve months. In addition, a warning that disclosure removal cannot be reversed as been added.	
Added Note field to the Update COI Information activity	When executing the Update COI Information activity for a person, reviewers can now add a note to document why they made changes to the person's COI information. These notes will display with the COI information on the Properties tab on the Person workspace.	
Reports		
Added new report with manually excluded disclosers	Added a new report Harvard Report: Manually Excluded Affiliates that includes all school affiliates that have been manually set to not disclose annually.	

What has changed...	What it means...	How it looks (as applicable) ...
Updated Migrated Disclosures report to filter out inactive users	Updated Harvard Report: Submitted Certifications with Migrated Disclosures That Have Not Been Updated to filter out users who are inactive. It is assumed that people who have left the university will not be updating any migrated disclosures.	
Miscellaneous		
Fixed bug related to Professional Services activities displaying when Professional Services was no longer selected	Previously, if a discloser removed the Professional Services or Employment category from a disclosure, the Disclosure Details page and certain reports would still display the previously selected types of Professional Services or Employment. Now these subcategories will no longer display if Professional Services or Employment is deselected.	
Updated must disclose annually logic to exclude people who are no longer investigators	If a person had been an investigator on an HMS or PHS+ project and were subsequently removed as investigators on that project, they were still included in the annual discloser population as long as the project was active. Now removing an investigator from an active project will remove the requirement for them to disclose annual for that project.	